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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,225	07/25/2001	Hannah Alexander	UVMO:011US/SLH	5639

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EXAMINER
KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,225	ALEXANDER ET AL.	
	Examiner	Art Unit	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-331* is/are pending in the application.

4a) Of the above claim(s) *31, 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-33 are pending in the present application. Claims 32 and 33 have been withdrawn from consideration. This Office action is in response to Paper No. 10, filed 15 Ma 2003.

Response to Amendment

The rejection of claims 1-31 under 35 U.S.C. 101 has been withdrawn in view of Applicant's amendment, filed 15 May 2003.

The rejection of claims 1-31 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of Applicant's amendment, filed 15 May 2003 deleting the language "for use in the prevention or treatment of cancer."

Claims 1-31 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Response to Arguments

Claims 1-31 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that "parts (i)-(iii) merely set forth three possible scenarios stemming from the performance of the claimed assay." Applicant's argument is noted, however, one could reasonably interpret the claims to also read that the qualities are inclusive of each other, thus still

rendering the claim unclear to one as to how a test agent can be both cytotoxic and not cytotoxic. The purpose of the present rejection under 35 U.S.C. 112, second paragraph is to overcome such ambiguities. The fact that Applicant can provide an alternative interpretation of the claim serves to punctuate its inherent ambiguity.

Applicant's argument regarding the term chemotherapeutic is found persuasive.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening agents that are cytotoxic to *Dictyostelium discoideum*, does not reasonably provide enablement for a method for screening agents that are chemopreventative or chemotherapeutic for cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's claims are directed to a method for screening agents comprising steps, which include contacting the amoebae, *Dictyostelium discoideum*, with a test agent and later assessing the test agent for toxicity on the cell. Applicant's method asserts that assessing the cytotoxicity of a mold to the test agent correlates to the cytotoxicity of said test agent to any cells. Thus, Applicant asserts that chemotherapeutics and chemopreventatives may be identified. Applicant's

method seeks to identify compounds that are cytotoxic to any cell type. However, Applicant has not shown how cytotoxicity or changes in expression of *repB, repD or APE* gene products relate to a compounds' value as a chemotherapeutic or chemopreventative.

Moreover, to identify compounds useful for treating or preventing cancer, Applicant must select an appropriate model that would translate to efficacy in at least killing mammalian cells generally and killing cells in a subject suffering from a specific cancer as well. Applicant's method uses *Dictyostelium discoideum* to screen for anticancer agents. However, Applicant has not shown any nexus between the cytotoxicity of an amoebae to the treatment and prophylaxis of cancer. The examples provided by Applicant in the specification also fail to provide a nexus between the cytotoxicity of an *Dictyostelium* and the cytotoxicity of other cells such that the agents may be chemotherapeutics or chemopreventatives. Applicant has provided an expression assay measuring the expression of *repB, repD* and *APE* in *Dictyostelium* and describes a cytotoxicity assay lacking any results on pages 23-24 of the specification. Neither of these examples provides the necessary data to overcome the unpredictability of the art. Applicant has not enabled the full scope of the present invention and is enabled for screening agents in *Dictyostelium*.

Insofar as Applicant's arguments to the rejection under 35 U.S.C. 112, first paragraph set forth in the prior Office action relate to the present rejection, they will be addressed below. Regarding the argument, that the present invention permits one to identify compounds with useful properties and potential uses. Applicant has still failed to provide evidence as to the state of the art which would lead the skilled artisan to use the present method to identify chemotherapeutics and chemopreventatives based on the cytotoxicity of test agents to

Dictyostelium and the expression of *repB, repD* and *APE* in *Dictyostelium*. Thus, the full scope of the present invention is not enabled. Second, Applicant regards the present situation as analogous to that presented in *Cross v. Iizuka,* 224 USPQ 739 (Fed. Cir. 1985) ("*Cross*"). In regard to the enablement issue, the court in *Cross* stated:

> The Board found that the knowledge as to the use of the pharmacological activity . . . in the fact that the system was a microsome system, microsome systems admittedly being known to those skilled in the art. . . . Thus, the dosage in the microsome assay milieu could be determined without inventive skill or undue experimentation. *Id.* 748

The situation in *Cross* differs from the present case because neither the pharmacological activity of the test agents are ~~not~~ known to those of skill in the art nor is the relationship between cytotoxicity of test agents to *Dictyostelium* and the expression of *repB, repD* and *APE* in *Dictyostelium* with the activity of the test agents as chemotherapeutics or chemopreventatives.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended the claims to recite the terms "potential chemotherapeutic" and "potential chemopreventative." This terminology is inherently vague and indefinite. Potential is a non-quantifiable and ambiguous term because "potential" is a matter of degree. Any agent, including something as benign as water, used in the method has the "potential" to be a

chemotherapeutic or chemopreventative. This term renders the present claims vague to one of skill in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers

for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
July 17, 2003

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600